

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

MIRIAM PASCAL,

Plaintiff,

V.

ELI LILLY & CO.,

Defendant.

08-CV-2040 (DLC)

ANSWER AND JURY TRIAL DEMANDED

Defendant Eli Lilly and Company (“Lilly”), by and through its counsel, hereby responds to Plaintiff’s Complaint (“Complaint”) as follows:

JURISDICTION AND VENUE

1. Paragraph 1 of the Complaint contains conclusions of law to which no answer is required.
2. Lilly is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 2 of the Complaint except admits that subject matter jurisdiction exists.
3. Lilly denies the allegations contained in Paragraph 3 of the Complaint, except admits that at certain times, Lilly has conducted business in this judicial district.

PARTIES

4. Lilly denies the allegations contained in Paragraph 4 of the Complaint, except admits that (i) it is a corporation organized and existing under the laws of the State of Indiana, with its principal place of business in Indianapolis, Indiana; and (ii) at certain times, it has been authorized to do business in the State of New York and in this judicial district.

5. Lilly is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 5 of the Complaint.

FACTUAL ALLEGATIONS

6. Lilly denies the allegations contained in Paragraph 6 of the Complaint, except admits that (i) Lilly researched, tested, developed, manufactured, marketed, and/or sold Zyprexa® to independent pharmaceutical wholesalers, for use only upon prescription by a licensed physician, in accordance with applicable laws and regulations and for its approved indications with warnings approved by the Food and Drug Administration of the United States Department of Health and Human Services (“FDA”) regarding the risks and benefits of the medication; and (ii) Zyprexa is approved by the FDA for the treatment of schizophrenia, the treatment of acute mixed or manic episodes associated with Bipolar I Disorder, and maintenance monotherapy for Bipolar Disorder. By way of further response, it is admitted that the combination of Zyprexa with lithium or valproate is indicated for the short-term treatment of acute manic episodes associated with Bipolar I Disorder.

7. Lilly denies the allegations contained in Paragraph 7 of the Complaint.

8. Lilly denies the allegations contained in Paragraph 8 of the Complaint, except is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 8 relating to the Plaintiff.

9. Lilly denies the allegations contained in Paragraph 9 of the Complaint, except is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 9 relating to the Plaintiff.

10. Lilly denies the allegations contained in Paragraph 10 of the Complaint, except admits that Lilly manufactured, marketed, and/or sold Zyprexa to independent pharmaceutical wholesalers for use only upon prescription by a licensed physician, in accordance with applicable

laws and regulations, and for its approved indications with FDA-approved warnings regarding the risks and benefits of the medication.

11. Lilly is without knowledge as to Plaintiff's meaning of the terms "higher failure rate," "incidence of causing the foregoing symptomology," and "similar medications," and therefore denies the allegations contained in Paragraph 11.

12. Lilly denies the allegations contained in Paragraph 12 of the Complaint, except admits that Lilly researched, tested, developed, manufactured, marketed, and/or sold Zyprexa to independent pharmaceutical wholesalers, for use only upon prescription by a licensed physician, in accordance with applicable laws and regulations and for its approved indications with FDA-approved warnings regarding the risks and benefits of the medication. By way of further response, Lilly is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 12 relating to the Plaintiff.

13. Lilly denies the allegations contained in Paragraph 13 of the Complaint.

14. Lilly denies the allegations contained in Paragraph 14 of the Complaint.

ANSWERING THE FIRST CAUSE OF ACTION

15. Lilly repeats and realleges with the same force and effect as though fully set forth here in full, its answer to each and every allegation contained in each paragraph incorporated by reference in Paragraph 15 of the Complaint.

16. Lilly denies the allegations contained in Paragraph 16 of the Complaint, except admits that Lilly researched, tested, developed, manufactured, marketed, and/or sold Zyprexa to independent pharmaceutical wholesalers, for use only upon prescription by a licensed physician, in accordance with applicable laws and regulations and for its approved indications with FDA-approved warnings regarding the risks and benefits of the medication. By way of further

response, Lilly is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 16 relating to the Plaintiff.

17. Lilly denies the allegations contained in Paragraph 17 of the Complaint, except admits that Lilly researched, tested, developed, manufactured, marketed, and/or sold Zyprexa to independent pharmaceutical wholesalers, for use only upon prescription by a licensed physician, in accordance with applicable laws and regulations, and for its approved indications with FDA-approved warnings regarding the risks and benefits of the medication.

18. Lilly denies the allegations contained in Paragraph 18 of the Complaint, except admits that Lilly researched, tested, developed, manufactured, marketed, and/or sold Zyprexa to independent pharmaceutical wholesalers, for use only upon prescription by a licensed physician, in accordance with applicable laws and regulations, and for its approved indications with FDA-approved warnings regarding the risks and benefits of the medication. By way of further response, Lilly is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 18 relating to the Plaintiff.

19. Lilly denies the allegations contained in Paragraph 19 of the Complaint.

20. Lilly is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 20 relating to the Plaintiff.

21. Lilly denies the allegations contained in Paragraph 21 of the Complaint.

22. Lilly denies the allegations contained in Paragraph 22 of the Complaint, except is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 22 relating to the Plaintiff.

23. Lilly denies the allegations contained in Paragraph 23 of the Complaint.

ANSWERING THE SECOND CAUSE OF ACTION

24. Lilly repeats and realleges with the same force and effect as though fully set forth here in full, its answer to each and every allegation contained in each paragraph incorporated by reference in Paragraph 24 of the Complaint.

25. Lilly denies the allegations contained in Paragraph 25 of the Complaint, except Lilly admits that it had a duty to exercise reasonable care in the research, testing, development, manufacture, marketing and sale of Zyprexa. Lilly denies that it breached such a duty.

26. Lilly denies the allegations contained in Paragraph 26 of the Complaint.

27. Lilly denies the allegations contained in Paragraph 27 of the Complaint.

28. Lilly denies the allegations contained in Paragraph 28 of the Complaint.

29. Lilly denies the allegations contained in Paragraph 29 of the Complaint.

30. Lilly denies the allegations contained in Paragraph 30 of the Complaint.

ANSWERING THE THIRD CAUSE OF ACTION

31. Lilly repeats and realleges with the same force and effect as though fully set forth here in full, its answer to each and every allegation contained in each paragraph incorporated by reference in Paragraph 31 of the Complaint.

32. Lilly denies the allegations contained in Paragraph 32 of the Complaint, except admits that it researched, tested, developed, manufactured, marketed, and/or sold Zyprexa to independent pharmaceutical wholesalers, for use only upon prescription by a licensed physician, in accordance with applicable laws and regulations, and for its approved indications with FDA-approved warnings regarding the risks and benefits of the medication.

33. Lilly denies the allegations contained in Paragraph 33 of the Complaint.

34. Lilly denies the allegations contained in Paragraph 34 of the Complaint.

35. Lilly is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 35 of the Complaint.

36. Lilly denies the allegations contained in Paragraph 36 of the Complaint.

37. Lilly denies the allegations contained in Paragraph 37 of the Complaint, except is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 37 relating to plaintiff or plaintiff's reliance.

ANSWERING THE FOURTH CAUSE OF ACTION

38. Lilly repeats and realleges with the same force and effect as though fully set forth here in full, its answer to each and every allegation contained in each paragraph incorporated by reference in Paragraph 38 of the Complaint.

39. Lilly denies the allegations contained in Paragraph 39 of the Complaint, except admits that it researched, tested, developed, manufactured, marketed, and/or sold Zyprexa to independent pharmaceutical wholesalers, for use only upon prescription by a licensed physician, in accordance with applicable laws and regulations, and for its approved indications with FDA-approved warnings regarding the risks and benefits of the medication.

40. Lilly denies the allegations contained in Paragraph 40 of the Complaint, except (i) admits that it researched, tested, developed, manufactured, marketed, and/or sold Zyprexa to independent pharmaceutical wholesalers, for use only upon prescription by a licensed physician, in accordance with applicable laws and regulations, and for its approved indications with FDA-approved warnings regarding the risks and benefits of the medication; (ii) is without knowledge or information as to Plaintiff's meaning of the term "systems," and (iii) is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations relating to the Plaintiff or patients.

41. Lilly denies the allegations contained in Paragraph 41 of the Complaint, except is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations relating to consumers' or plaintiff's reliance.

42. Lilly is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 42 of the Complaint.

43. Lilly denies the allegations contained in Paragraph 43 of the Complaint.

44. Lilly denies the allegations contained in Paragraph 44 of the Complaint.

45. Lilly denies the allegations contained in Paragraph 45 of the Complaint.

46. Lilly denies the allegations contained in Paragraph 46 of the Complaint.

ANSWERING THE FIFTH CAUSE OF ACTION

47. Lilly repeats and realleges with the same force and effect as though fully set forth here in full, its answer to each and every allegation contained in each paragraph incorporated by reference in Paragraph 47 of the Complaint.

48. Lilly is without knowledge as to Plaintiff's meaning of the terms "assertions and/or promises of fact" and "superior material" and therefore denies the allegations contained in Paragraph 48.

49. Lilly denies the allegations contained in Paragraph 49 of the Complaint.

50. Lilly denies the allegations contained in Paragraph 50 of the Complaint, except is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 50 relating to plaintiff.

51. Lilly denies the allegations contained in Paragraph 51 of the Complaint.

52. Lilly denies the allegations contained in Paragraph 52 of the Complaint.

53. Lilly denies the allegations contained in Paragraph 53 of the Complaint.

ANSWERING THE SIXTH CAUSE OF ACTION

54. Lilly repeats and realleges with the same force and effect as though fully set forth here in full, its answer to each and every allegation contained in each paragraph incorporated by reference in Paragraph 54 of the Complaint.

55. Lilly denies the allegations contained in Paragraph 55 of the Complaint, except Lilly admits that it had a duty to exercise reasonable care in the research, testing, development, manufacture, marketing, labeling and sale of Zyprexa. Lilly denies that it breached such a duty.

56. Lilly denies the allegations contained in Paragraph 56 of the Complaint, except Lilly admits that it had a duty to exercise reasonable care in the research, testing, development, manufacture, marketing and sale of Zyprexa. Lilly denies that it breached such a duty.

57. Lilly denies the allegations contained in Paragraph 57 of the Complaint.

58. Lilly denies the allegations contained in Paragraph 58 of the Complaint.

59. Lilly denies the allegations contained in Paragraph 59 of the Complaint.

60. Lilly denies the allegations contained in Paragraph 60 of the Complaint.

FIRST AFFIRMATIVE DEFENSE

61. The Complaint fails to state a claim upon which relief can be granted against Lilly.

SECOND AFFIRMATIVE DEFENSE

62. Plaintiff's claims are barred, in whole or in part, by the applicable statutes of limitations.

THIRD AFFIRMATIVE DEFENSE

63. Some or all of Plaintiff's claims are barred by the learned intermediary and/or sophisticated user doctrines. At all relevant times herein, Plaintiff's prescribing physicians were

in the position of sophisticated purchasers, fully knowledgeable and informed with respect to the risks and benefits of Zyprexa.

FOURTH AFFIRMATIVE DEFENSE

64. The injuries, damages, and losses alleged in the Complaint, none being admitted, were caused in whole or in part by the negligence of the Plaintiff and/or others, over whom Lilly exercised no control, had no opportunity to anticipate or right to control, and with whom Lilly had no legal relationship by which liability could be attributed to it because of the actions of the Plaintiff and/or others, which by comparison was far greater than any conduct alleged as to Lilly.

FIFTH AFFIRMATIVE DEFENSE

65. Plaintiff's alleged loss, damage, injury, harm, expense, diminution, or deprivation alleged, if any, was caused in whole or in part by Plaintiff's failure to exercise reasonable care and diligence to mitigate her alleged damages.

SIXTH AFFIRMATIVE DEFENSE

66. Plaintiff's claims are preempted by federal law in that Zyprexa was researched, tested, developed, manufactured, labeled, marketed and sold in a manner consistent with the state of the art at the pertinent time and approved by the FDA.

SEVENTH AFFIRMATIVE DEFENSE

67. Some or all of Plaintiff's claims are barred by the doctrines concerning unavoidably unsafe products, including, but not limited to, the operation of comments j and k to Section 402A of the Restatement (Second) of Torts and/or barred by the Restatement (Third) of Torts.

EIGHTH AFFIRMATIVE DEFENSE

68. Plaintiff's breach of warranty claims are barred because there is no privity of contract between the Plaintiff and Lilly; Plaintiff failed to give timely notice of any alleged

breach of warranty to Lilly; Plaintiff did not reasonably rely upon any alleged warranty; Plaintiff failed to satisfy all conditions precedent or subsequent to the enforcement of such warranty; and the warranty was appropriately disclaimed, excluded or modified.

NINTH AFFIRMATIVE DEFENSE

69. Plaintiff's claims are barred in whole or in part by the applicable provisions of the United States Constitution, the New York Constitution and/or the applicable Constitution of any other State or Commonwealth of the United States whose laws might be deemed controlling in this case. These provisions include, but are not limited to, the First Amendment to the Constitution of the United States and/or Article 1, § 8 of the New York Constitution because Lilly's commercial speech regarding Zyprexa was neither false nor misleading.

TENTH AFFIRMATIVE DEFENSE

70. Lilly alleges that Plaintiff and/or Plaintiff's Legal Guardian was fully informed of the risks of the use of the product made the subject of this action by the treating physicians, and the informed consent given by Plaintiff or Plaintiff's Legal Guardian is pleaded as an affirmative defense.

ELEVENTH AFFIRMATIVE DEFENSE

71. To the extent Plaintiff makes a claim for punitive damages, such claim violates, and it is therefore barred by, the Fourth, Fifth, Sixth, Eighth and Fourteenth Amendments to the Constitution of the United States of America on grounds including the following:

- a. It is a violation of the Due Process and Equal Protection Clauses of the Fourteenth Amendment of the United States Constitution to impose punitive damages, which are penal in nature, against a civil defendant upon the Plaintiffs satisfying a burden of proof which is less than the "beyond a reasonable doubt" burden of proof required in criminal cases;

- b. Procedures pursuant to which punitive damages are awarded may result in the award of joint and several judgments against multiple defendants for different alleged acts of wrongdoing, which infringes upon the Due Process and Equal Protection Clauses of the Fourteenth Amendment of the United States Constitution;
- c. The procedures pursuant to which punitive damages are awarded fail to provide a reasonable limit on the amount of the award against defendant, which thereby violates the Due Process Clause of the Fourteenth Amendment of the United States Constitution;
- d. The procedures pursuant to which punitive damages are awarded fail to provide specific standards for the amount of the award of punitive damages which thereby violates the Due Process Clause of the Fourteenth Amendment of the United States Constitution;
- e. The procedures pursuant to which punitive damages are awarded result in the imposition of different penalties for the same or similar acts, and thus violate the Equal Protection Clause of the Fourteenth Amendment of the United States Constitution;
- f. The procedures pursuant to which punitive damages are awarded permit the imposition of punitive damages in excess of the maximum criminal fine for the same or similar conduct, which thereby infringes upon the Due Process Clause of the Fifth and Fourteenth Amendments and the Equal Protection Clause of the Fourteenth Amendment of the United States Constitution;

- g. The procedures pursuant to which punitive damages are awarded permit the imposition of excessive fines in violation of the Eighth Amendment of the United States Constitution;
- h. The award of punitive damages to Plaintiff in this action would constitute a deprivation of property without due process of law; and
- i. The procedures pursuant to which punitive damages are awarded permit the imposition of an excessive fine and penalty.

TWELFTH AFFIRMATIVE DEFENSE

72. To the extent Plaintiff makes a demand for punitive or exemplary damages, Lilly specifically incorporates by reference all standards of limitations regarding the determination and enforceability of punitive damages awards, including but not limited to, those standards of limitation which arose in *BMW of North America v. Gore*, 517 U.S. 559 (1996); *Cooper Industries, Inc. v. Leatherman Tool Group, Inc.*, 532 U.S. 424 (2001); and *State Farm Mutual Automobile Ins. Co. v. Campbell*, 538 U.S. 408 (2003).

THIRTEENTH AFFIRMATIVE DEFENSE

73. Plaintiff's claims are barred and/or this Court should defer this matter, in whole or in part, pursuant to the doctrine of primary jurisdiction, in that FDA is charged under the law with regulating prescription drugs, including Zyprexa, and is specifically charged with determining the content of the warnings and labeling for prescription drugs. The granting of the relief prayed for in the Plaintiff's Complaint would impede, impair, frustrate or burden the effectiveness of such federal law and would violate the Supremacy Clause (Art. VI, cl. 2) of the United States Constitution.

FOURTEENTH AFFIRMATIVE DEFENSE

74. To the extent Plaintiff's claims are based on alleged misrepresentations made to the FDA, such claims are barred pursuant to *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001).

FIFTEENTH AFFIRMATIVE DEFENSE

75. The injuries or damages allegedly sustained by Plaintiff can be attributed to several causes and accordingly should be apportioned among the various causes according to respective contribution of each such cause to the harm sustained, if any. If any liability is found against Lilly, then said liability will constitute 50% or less of the total liability assigned to all persons liable, and as such, the liability of Lilly to Plaintiff for non-economic loss shall be limited, and shall not exceed Lilly's equitable share.

SIXTEENTH AFFIRMATIVE DEFENSE

76. Any verdict or judgment rendered against Lilly must be reduced by those amounts that have been, or will, with reasonable certainty, replace or indemnify Plaintiff, in whole or in part, for any claimed economic loss, from any collateral source such as insurance, social security, workers' compensation or employee benefit programs.

SEVENTEENTH AFFIRMATIVE DEFENSE

77. Lilly is entitled to the benefit of all defenses and presumptions contained in, or arising from, any rule of law or statute of any other state whose substantive law might control any of the claims in the action.

EIGHTEENTH AFFIRMATIVE DEFENSE

78. Based on the state of scientific, medical, and technological knowledge existing at the time Zyprexa was allegedly ingested by Plaintiff, it was reasonably safe for its normal and

foreseeable use at all relevant times, or in light of existing reasonably available medical, scientific, and technological knowledge.

NINETEENTH AFFIRMATIVE DEFENSE

79. Any injuries or expenses incurred by Plaintiff were not caused by Lilly, but may have been proximately caused, in whole or part, by the unforeseen alteration, unintended use, misuse or abuse of the products referenced in Plaintiff's complaint.

TWENTIETH AFFIRMATIVE DEFENSE

80. To the extent that Plaintiff requests attorneys' fees, such a request is improper under applicable law.

TWENTY-FIRST AFFIRMATIVE DEFENSE

81. As Zyprexa is not a consumer good, Plaintiff's allegations based on consumer warranty laws are not applicable as a matter of law.

TWENTY-SECOND AFFIRMATIVE DEFENSE

82. Upon information and belief, some or all of the injuries alleged in the Complaint were caused by preexisting medical conditions, subsequent medical conditions, and the natural course of those conditions of the plaintiff, by an idiosyncratic reaction, operation of nature, or act of God, for which Lilly is not responsible.

TWENTY-THIRD AFFIRMATIVE DEFENSE

83. One or more of Plaintiff's claims are barred by the doctrine of release.

Lilly hereby gives notice that it intends to rely upon such other defenses as may become available or apparent during the course of discovery and thus reserves the right to amend this list to assert such defenses.

WHEREFORE, defendant Eli Lilly and Company requests that Plaintiff's Complaint, and all claims alleged therein, be dismissed with prejudice, that Lilly be awarded the costs,

disbursements and attorneys' fees incurred in the defense of this action, and that Lilly be granted any other relief to which it may be entitled.

Dated: New York, New York
April 2, 2008

PEPPER HAMILTON LLP

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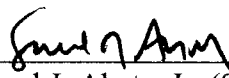
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JURY DEMAND

Lilly demands a trial by jury on all issues triable in this action.



Samuel J. Abate, Jr. (SA 0915)